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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,165	11/19/2007	Mitsuhiro Shikida	450104-05892	5637

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EXAMINER	
PREGLER, SHARON	
ART UNIT	PAPER NUMBER
1797	
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08/19/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,165	SHIKIDA ET AL.	
	Examiner	Art Unit	
	Sharon Pregler	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Examiner acknowledges Applicant's response filed 6/16/2010 containing remarks and amendments to the claims.

2. Claims 17-28 are pending. Claims 1-16 are cancelled.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. ***Claims 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein US Patent 6,432,630 in view of Ward et al. US Pre-Grant***

Publication 2004/0018611 in further view of Ishiguro et al. JP 2003-050245 (already of record).

7. **Regarding claim 17, Blankenstein teaches** an chemical analytic apparatus *(microflow system 1, figure 1, column 12 line 62 – column 13 line 12)* which performs various kinds of processing for analyzing very small droplets chemically *(column 1 lines 20-30)*, including:

8. in a condition where magnetic ultrafine particles *(magnetically stained particles 12 in sample 9, figure 1)* are mixed to a droplet *(column 3 line 65 – column 4 line 10; column 12 lines 50-60, figure 1)*,

9. a conveyance means, wherein *(flow channel 5, figure 1 column 12 lines 60-65)* the droplet, to which said magnetic ultrafine particles were mixed is conveyed in another liquid *(buffers 10 & 11; it is well known that buffers may be fluid; enter flow channel, column 13 lines 1-5; furthermore, the magnet drives magnetic fluid to chamber 37 where it may contain washing fluid or reagents for reactions or analysis; column 17 lines 9-13)*, for processing of chemical analysis, due to attraction by *(field generating means with a magnet 8, column 13 lines 1-5)* said magnetic ultrafine particles to the magnetic field of the conveyance means *(attracted to magnet, figure 6)*; and

10. a processing means *(detection means 16, figure 2)* by which operations for processing of chemical analysis are performed one by one in the process in which the droplet to which said magnetic ultrafine particles were mixed is conveyed by said conveyance means *(column 12 line 62 – column 13 line 12, figure 1)*, wherein

11. plural kinds of the droplets *(the droplets are considered as intended use and do not add weight to the apparatus claims for patentability)* to which said magnetic ultrafine particles are mixed and of only the droplets are provided, and said processing means includes small compartments *(collection chamber 37, column 16 lines 35-45, figure 7)* separated by plural bulkheads *(protrusion of outlet 6 & 7, figure 1)*, and said plural kinds of the droplets to which said magnetic ultrafine particles were mixed and of only the droplets are arranged in said small compartments *(collection chamber 37)*, and

12. an optional droplet to which said magnetic ultrafine particles are mixed and which is arranged in an optional small compartment *(the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1)* is conveyed by said conveyance means, by passing through each bulkhead separating one small compartment from another *(figure 6 shows the protrusions or bulkheads separating the compartments, or channels 5 & 6, figure 9 shows multiple bulkheads and compartments in a series, column 13 lines 1-10)*,

and a chemical reactive operation itself or part of the operation is performed by uniting the optional droplet *(collection chamber 37 may contain a liquid or reagent fluid, inherently droplet, for further chemical reactions or analysis, column 17 lines 9-13)* with the another droplet out of said plural kinds arranged in the other small compartments. *(See figure 1, 6-7, column 1 lines 20-30, column 3 line 65 – column 4 line 10, column 12 lines 50-65, column 13 lines 1-15 & 40-50, column 16 lines 35-45)*.

13. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein is a protrusion within the channel and effectively sorts fluid as the bulkhead described in the specification where it separates the fluid into another compartment *(outlet 6)*. Furthermore Ward teaches it would have been obvious to have bulkheads valleys, pits, or protrusions *(See Ward Figure 7 & [0289]-[0290])* to define chambers for separation for the benefit of separating molecules based on molecular size, shape, and/or charge *([0134])*.

14. Therefore it would have been obvious to modify the channel of Blankenstein with pits or bulkheads of Ward for the benefit of separating molecules based on molecular size, shape, and/or charge.

15. Blankenstein does not teach the magnet or conveyance means moving in a direction while applying a magnetic field, rather the magnet (8) is stationary as it's applying the magnetic field.

16. In the analogous art of particle separation in fluids, Ishiguro teaches a magnet that translate *(magnet 13, figure 3, [0011])* that moves rightward in the fluidic apparatus that moves magnetic fluid that was introduced into microchannels *(3)* towards capacity portions *(1, 2)*, for the benefit of driving magnetic particles across a distance within a channel.

17. It would have been obvious to one of ordinary skill in the art to use a moving magnet of Ishiguro in the apparatus of Blankenstein to drive magnetic particles across a distance within a channel.

18. **Regarding claim 18, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein

19. when the optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed and which is arranged in an optional small compartment is conveyed to said other small compartments *(the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1)* by said conveyance means by passing through each bulkhead separating one small compartment from another *(figure 6 shows the protrusions*

or bulkheads separating the compartments, or channels 5 & 6, figure 9 shows multiple bulkheads and compartments in a series, column 13 lines 1-10),

20. the optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed is separated *(separation occurs after magnet 8 toward sort outlet 6, figure 1)* to a droplet that includes said magnetic ultrafine particles *(column 13 lines 5-9)* and the droplet that does not include said magnetic ultrafine particles *(column 13 lines 9-12)*, by using physical and chemical characteristics such as wettability and surface tension of said optional droplet *(column 13 lines 13-20)*.

21. **Regarding claim 19, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein

22. by controlling the magnetic field which is externally applied to the droplet to which said magnetic ultrafine particles are mixed, said magnetic ultrafine particles are dispersed and cohered in the inside of the droplet, and also the operations fro processing of chemical analysis of the droplet to which said magnetic ultrafine particles are mixed are performed. *(Column 3 line 65 – column 4 line 10 & column 5 line 60-65, column 6 line 20-35, & column 9 lines 10-40).*

23. **Regarding claims 20 & 26, Blankenstein teaches** the chemical analytic apparatus above, wherein but does not teach the physical and chemical reaction control by light, heat or pH is used.

24. In the analogous art of magnetic separation in microfluidics Ward teaches reactions with light *(Ward [0049])*, heat *(raising temperature of the reaction in Ward [0143])*, and pH *(pH changes in Ward [0143])* for the benefit of nucleic acid amplification *([0143])* in order to conjugate to a magnetic particle *([0142]).*

25. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the reactions of Ward with the apparatus of Blankenstein for the benefit of nucleic acid amplification in order to conjugate to a magnetic particle *([0142])*.

26. **Regarding claim 21, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein

27. in the condition where a specimen for performing chemical reactive operation adhered *(magnetically stained particles, column 3 line 67 column 4 line 9)* to surfaces of said magnetic ultrafine particles, said magnetic ultrafine particles are used as a carrier to perform the chemical reactive operation to said specimen *(column 13 lines 1-15)*.

28. **Regarding claim 22, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein

29. by combining a plurality of said small compartments *(the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1)* which are separated by plural bulkheads and which become said processing means, at least a series of chemical reactive operation by reaction, separation and dilution to a specimen that adhered to surfaces of said magnetic ultrafine particles is performed. *(See figure 1, & column 1 lines 20-30)*.

30. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein is a protrusion within the channel and effectively sorts fluid as the bulkhead described in the specification where it separates the fluid into another compartment *(outlet 6)*. Furthermore Ward teaches it would have been obvious to have bulkheads valleys, pits, or protrusions *(See Ward Figure 7 & [0289]-[0290])* to define chambers for separation for the benefit of separating molecules based on molecular size, shape, and/or charge *([0134])*.

31. Therefore it would have been obvious to modify the channel of Blankenstein with pits or bulkheads of Ward for the benefit of separating molecules based on molecular size, shape, and/or charge.

32. **Regarding claim 23, Blankenstein teaches** a chemical analytic apparatus *(microflow system 1, figure 1, column 12 line 62 – column 13 line 12)* which performs various kinds of processing for analyzing very small droplets chemically *(column 1 lines 20-30)*, including:

33. in a condition where magnetic ultrafine particles *(magnetically stained particles 12 in sample 9, figure 1)* are mixed to a droplet *(column 3 line 65 – column 4 line 10; column 12 lines 50-60, figure 1)*,

34. a conveyance step *(flowing through flow channel 5, figure 1 column 12 lines 60-65)*, wherein the droplet to which said magnetic ultrafine particles were mixed is conveyed in another liquid *(buffers 10 & 11; it is well known that buffers may be fluid; enter flow channel, column 13 lines 1-5)*, for processing of the chemical analysis, *(field generating means with a magnet 8, column 13 lines 1-5)* due to attraction by said magnetic ultrafine particles to the magnetic field of conveyance unit; and

35. processing steps *(detection means 16, figure 2)* by which operations for processing of chemical analysis are performed one by one in the process in which the droplet to which said magnetic ultrafine particles were mixed is conveyed by said conveyance step *(column 12 line 62 – column 13 line 12, figure 1)*, wherein

36. plural kinds of the droplets to which said magnetic ultrafine particles are mixed and of only the droplets are provided, and the processing conditions by said processing steps are formed in small compartments *(collection chamber 37, column 16 lines 35-45, figure 7)* separated by plural bulkheads *(flow through controlled by valves in column 7 lines 35-45)*, and said plural kinds of droplets to which said magnetic ultrafine particles of the were mixed or only the droplets are arranged in said small compartments, *(collection chamber 37)*, and

37. an optional droplet out of said plural kinds of droplets *(see below)* to which said magnetic ultrafine particles were mixed and which is arranged in an optional small compartment *(the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1)* is conveyed by passing through each bulkhead separating one said small compartment from another, and a chemical reactive operation itself or part of the operation is performed by uniting the optional droplet with another droplet out of said plural kinds arranged in the other small compartments. *(See figure 1, 6-7, column 1 lines 20-30, column 3 line 65 – column 4 line 10, column 12 lines 50-65, column 13 lines 1-15 & 40-50, column 16 lines 35-45).*

38. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein is a protrusion within the channel and effectively sorts fluid as the bulkhead described in the specification where it separates the fluid into another compartment *(outlet 6)*. Furthermore Ward teaches it would have been obvious to have bulkheads valleys, pits, or protrusions *(See Ward Figure 7 & [0289]-[0290])* to define chambers for separation for the benefit of separating molecules based on molecular size, shape, and/or charge *([0134])*.

39. Therefore it would have been obvious to modify the channel of Blankenstein with pits or bulkheads of Ward for the benefit of separating molecules based on molecular size, shape, and/or charge.

40. Blankenstein does not teach the magnet or conveyance unit moving in a direction while applying a magnetic field, rather the magnet (8) is stationary as it's applying the magnetic field.

41. In the analogous art of particle separation in fluids, Ishiguro teaches a magnet that translate *(magnet 13, figure 3, [0011])* that moves rightward in the fluidic apparatus that moves magnetic fluid that was introduced into microchannels *(3)* towards capacity portions *(1, 2)*, for the benefit of driving magnetic particles across a distance within a

channel. It would be an inherent feature of Ishiguro to include a conveyance unit or a means for translating the magnet.

42. It would have been obvious to one of ordinary skill in the art to use a moving magnet of Ishiguro in the apparatus of Blankenstein to drive magnetic particles across a distance within a channel.

43. **Regarding claim 24, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein

44. when the optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed and which is arranged in the optional small compartment is conveyed to said other small compartments by said conveyance step by passing through each bulkhead separating one small compartment from another *(figure 6 shows the protrusions or bulkheads separating the compartments, or channels 5 & 6, figure 9 shows multiple bulkheads and compartments in a series, column 13 lines 1-10))*,

45. the optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed is separated *(separation occurs after magnet 8 toward sort outlet 6, figure 1)* to the droplet that includes said magnetic ultrafine particles *(column 13 lines 5-9)* and a droplet that does not include said magnetic ultrafine particles *(column 13 lines 9-12)*, by using physical and chemical characteristics such as wettability and surface tension of said optimal droplet. *(column 13 lines 13-20)*.

46. **Regarding claim 25, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein

47. by controlling the magnetic field *(field by magnet 8)* which is externally applied to the droplet to which said magnetic ultrafine particles are mixed, said magnetic ultrafine particles are dispersed and cohered in the inside of the droplet, and also the operation of a specimen that adhered to surfaces of said magnetic ultrafine particles is performed. *(Column 3 line 65 – column 4 line 10 & column 5 line 60-65, column 6 line 20-35, & column 9 lines 10-40)*.

48. **Regarding claim 27, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein

49. in the condition where a specimen for performing chemical reactive operation adhered *(magnetically stained particles, column 3 line 67 column 4 line 9)* to surfaces of said magnetic ultrafine particles, said magnetic ultrafine particles are used as a carrier to perform the chemical reactive operation to said specimen. *(column 13 lines 1-15)*.

50. **Regarding claim 28, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein

51. by combining a plurality of said small compartments *(the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1)* which are separated by plural bulkheads and which form the processing conditions by said processing steps, at least a series of chemical reactive operation by at least reaction, separation and dilution to the specimen that adhered to surfaces of said magnetic ultrafine particles is performed. *(See figure 1 & column 1 lines 20-30).*

52. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein acts as a bulkhead described in the specification where it separates the fluid into another compartment *(outlet 6)*. It would have been obvious to have protrusions or bulkheads to define chambers for separation.

Response to Arguments

53. Applicant's arguments with respect to claims 17-28 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendment.

54. Regarding Applicant's argument that Ward merely teaches a microchannel containing a dome structure, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, the Examiner relies on Wards teaching of ridges, pits, and valleys that correspond to the microchannels *in addition* to the related bulkheads *(the arrowhead-shaped channel intersection of 5 & 6)* depicted in Blankenstein that effectively provides a physical barrier to aid in separating the magnetic particles from a buffer solution or other liquid *(Blankenstein figure 6)*.

55. Regarding Applicant's argument that the combination of Blankenstein and Ward would merely suggest to have a stationary magnet attract particles in a flow channel and to form a flow channel taught by Ward, thus nothing in the combination shows, teaches or suggests a conveyance means/unit applying a magnetic field and moving in a direction such that droplets, mixed with magnetic ultrafine particles are conveyed in another liquid due to the attraction to the magnetic field. Examiner has relied on the teaching of Ishiguro above,

as necessitated by amendment, where a magnet moves transversely with the magnetic particles in a channel. It would have been obvious to one of ordinary skill in the art to move a magnet to apply the magnetic field transversely over a given channel length.

Conclusion

56. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Pregler whose telephone number is (571)270-5051. The examiner can normally be reached on Mon - Fri 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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